



# UNITED STATES PATENT AND TRADEMARK OFFICE

(M)

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,884	01/24/2002	Han Chang	D0076 NP	3042

23914 7590 03/08/2004  
STEPHEN B. DAVIS  
BRISTOL-MYERS SQUIBB COMPANY  
PATENT DEPARTMENT  
P O BOX 4000  
PRINCETON, NJ 08543-4000

EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/056,884	CHANG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,8,9 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,8,9 and 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4,8,9 and 16-19 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The Response and Amendment filed 14 January 2004 has been received and entered in full. Claims 5-7, 10-15, and 20-25 have been cancelled. Claims 1, 4, 8, and 16 have been amended. Claims 1-4, 8, 9, and 16-19 are under examination.
2. The Statement of Public Access to ATCC Deposit No. PTA-2966 filed 14 January 2004 has been received and entered.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections And/Or Rejections***

4. The Objections to the Specification as set forth at ¶3-7 pp. 2-3 of the previous Office Action (17 September 2003) are *withdrawn* in view of Applicant's amendments (14 January 2004).
5. The Objections to the Claims as set forth at ¶8-10 pp. 3 of the previous Office Action (17 September 2003) are *withdrawn* in view of Applicant's amendments (14 January 2004).
6. The Rejection of claim 1 under 35 U.S.C. §112 ¶1 as set forth at ¶27-31 pp. 18-19 of the previous Office Action (17 September 2003) are *withdrawn* in view of Applicant's Statement of Public Access to ATCC Deposit No. PTA-2966 filed 14 January 2004.

***Maintained Objections And/Or Rejections***

7. Claims **1-4, 8, 9, and 16-19** are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a well-asserted utility or a well-established utility for the reasons set forth at ¶¶ 11-15 pp. 4-13 of the previous Office Action (17 September 2003).

8. Applicant traverses this rejection on the following grounds: **(a)** rigorous correlation need not be shown in order to establish practical utility {Fukikawa v. Wattanasin, 93 F.3d 1559, 1565, 39 USPQ 2d 1895, 1900 (Fed. Cir. 1996)}, **(b)** SEQ ID NO: 1 is expressed in the brain, testis, and pancreas and is a potassium channel (V.A.), **(c)** SEQ ID NO: 1 shares homology with K+Hnov28, K+Hnov27, *Drosophila* CG10830 protein, *Caenorhabditis* K+ channel, and K+Hnov27 and is a potassium channel (V.B.), **(d)** the Specification lists a large number of potassium ligands, diseases; Example 56 wherein the claimed sequence is similar to the NFκB; it is a “real-world” utility (V.C.), **(e)** the Specification includes instructions for identifying the cognate ligand of SEQ ID NO: 1 as well as a list of disease that may be associated with SEQ ID NO: 1 (V.D.), **(f)** a list of diseases and conditions that could be treated with a modulator (a drug) of SEQ ID NO: 1 is disclosed and substantial significant research would not be required, (V.E.), **(g)** the homology between the genes in Figure 4 and SEQ ID NO: 1 showed that is a potassium channel β subunit polypeptide; diseases are named that “can be employed in the cited utility”; not all probes and primers can be used for the claimed sequence (V.F.), **(h)** pages 157-178 list disease and conditions for which “may be treatable” using SEQ ID NO: 1 (V.G.), **(i)** SEQ ID NO: 1 may be used to make a gene chip (V.H.), **(j)** the claimed sequences can be used to make antisense molecules (V.I.), **(k)** SEQ ID NO: 1 is expressed in testis, brain, and pancreas; it shares sequence homology with other genes (Figure 4) (V.J.), **(l)** the Specification teaches how to make

Art Unit: 1647

fusion proteins with “real-world applications” (V.K.) **(m)** host cells may be made using SEQ ID NO: 1; recombinant proteins expressed (V.L.) **(n)** the Specification teaches how to use the claimed sequence as in a chromosomal mapping protocol (V.M.), **(o)** SEQ ID NO: 1 could be used as a molecular weight marker for any one of a number of diseases and conditions (V.N.) **(p)** guidance on how to make hybridization probes are included; *Drosophila* data suggests a role for the claimed sequence (V.O.), **(q)** SEQ ID NO: 1 may be used to make transgenic animals (V.P.), and **(r)** Applicant repeats assertions from Specification (V.A.-V.P.). Applicant’s arguments have been taken into consideration and are not found persuasive for the following reasons.

9. On “**(a)**”, 35 U.S.C. 101 has three requirements: (1) credible, (2) specific, (3) substantial. Applicant’s claimed invention is credible as potassium channel beta subunits do exist and therefore is plausible. However, Applicant’s claimed invention fails to fulfill the final two requirements, specific and substantial. As currently presented neither evidence nor any correlation between SEQ ID NO: 1 and the polypeptide encoded by it, SEQ ID NO: 2, exists between any known or characterized potassium channel beta subunit. Applicant has asserted that SEQ ID NO: 1 has utility in the absence of evidence.

10. On “**(b)**”, the Specification teaches that SEQ ID NO: 1 is expressed in many tissues, however, this is insufficient to satisfy the specific requirement of 35 U.S.C. 101. It is not taught under what conditions, what levels, what isoforms, splice variants, or in which species is expressed. Applicant has asserted based on sequence homology that SEQ ID NO: 1 is a potassium channel. As discussed in the previous Office Action (17 September 2003) sequence homology is not predictive of structure or function for potassium channels which are a large and diverse family. Therefore the assertion is a suggestion for SEQ ID NO: 1’s function, as further

experimentation is required to confirm SEQ ID NO: 1's identity. Thusly the asserted utility is not substantial.

11. On “(c)”, Figures 2 and 4 show sequence homology between SEQ ID NO: 1 and potassium channels thus the asserted utility is credible. However, Applicant has failed to show which potassium channel SEQ ID NO: 1. It is not taught whether it is voltage-gated, time-gated, what ligand it is, or where it is expressed. A significant amount of experimentation to confirm the suggested identity of SEQ ID NO: 1 is required to establish specificity. As discussed in the previous Office Action (17 September 2003) sequence homology is not predictive of structure or function for potassium channels which are a large and diverse family. Therefore the assertion is a suggestion for SEQ ID NO: 1's function. As further experimentation is required to confirm SEQ ID NO: 1's identity and function the asserted utility is not substantial.

12. On “(d)”, the lists of ligands and disease in the Specification do not bestow specificity to SEQ ID NO: 1. Applicant has provided potential ligands and possible diseases for SEQ ID NO: 1, no specificity has been established. It remains to be seen which ligand and which disease matches with SEQ ID NO: 1. This can only be accomplished through additional extensive experimentation. Thus this asserted utility is neither specific nor substantial. Example 56 is of no relevance to SEQ ID NO: 1. It demonstrates neither function nor identity for SEQ ID NO: 1. This can only be accomplished through additional extensive experimentation. Thus this asserted utility is neither specific nor substantial. The question of “real-word” utility is not relevant as the asserted utility is credible therefore it is a “real-word” utility. However it is not specific or substantial and these can only be established through additional extensive experimentation. Thus this asserted utility while credible, is neither specific nor substantial.

13. On “(e)”, instructions in lieu of data are an invitation to experiment and identify the ligand. the Examiner takes note of this admission by Applicant that SEQ ID NO: 1 has no known ligand as it must be identified by using the instructions provided by Example 9. Further note is taken of the “extensive list of disease the may be associate with the claimed sequence”, again, no specific disease is disclosed and can only be made certain through additional extensive experimentation. Thus this asserted utility is neither specific nor substantial.

14. On “(f)”, instructions in lieu of data are an invitation to experiment and identify the ligand. the Examiner again takes note of this admission by Applicant that SEQ ID NO: 1 is not associated with any known disease or condition and its role in any of such must be identified. The role of SEQ ID NO: 1 in any disease or condition that is disclosed can only be made certain through additional extensive experimentation. Thus this asserted utility is neither specific nor substantial.

15. On “(g)”, as discussed in the previous Office Action (17 September 2003) sequence homology is not predictive of structure or function for potassium channels which are a large and diverse family. Therefore the assertion is a suggestion for SEQ ID NO: 1’s function. As further experimentation is required to confirm SEQ ID NO: 1’s identity and function the asserted utility is not substantial. The Specification lists an “extensive list of disease the may be associate with the claimed sequence” but no specific disease is disclosed and can only be made certain through additional extensive experimentation. Finally, since the claimed sequence does not have any utility any probes and primers made with it also lack utility. Thus this asserted utility is neither specific nor substantial.

Art Unit: 1647

16. On “(h)”, the Examiner notes that Applicant acknowledges no specific disease or conditions that SEQ ID NO: 1 is useful for treating. The Specification lists a ponderous number of disease and conditions as an invitation to experiment. First the identity and function of SEQ ID NO: 1 must be established. Then significant research in must be undertaken to use SEQ ID NO: 1 in gene therapy {see previous Office Action (17 September 2003)}.

17. On “(i)”, this asserted utility is credible, but not specific or substantial. The specification discloses an enormous range of tissues both diseased and healthy (pp. 157-178) and the relative levels of SEQ ID NO: 1 expression (Figure 2). However it is not clear that SEQ ID NO: 1 expression is specific for any given tissue. In addition, tissues can express a wide range of transcripts which may or may not be translated into fully function all proteins. Therefore this asserted utility is not specific as no specific tissue is disclosed. Also this utility is generic and can be applied to any given polynucleotide. This utility is also not substantial because there is not known function, no known disease, condition, injury, or use associated with SEQ ID NO: 1. A skilled artisan would be confronted by an undue experimentation burden to discern which tissues specifically express SEQ ID NO: 1, its function, its identity, and what the relevance is (i.e. involvement in a particular disease).

18. On “(j)”, this asserted utility is credible, but not specific or substantial. The specification discloses an enormous range of tissues both diseased and healthy (pp. 157-178) and the relative levels of SEQ ID NO: 1 expression (Figure 2). However it is not clear that SEQ ID NO: 1 expression is specific for any given tissue. In addition, tissues can express a wide range of transcripts which may or may not be translated into fully function all proteins. Therefore this asserted utility is not specific as no specific tissue is disclosed. Also this utility is generic and can



Art Unit: 1647

be applied to any given polynucleotide. This utility is also not substantial because there is not known function, no known disease, condition, injury, or use associated with SEQ ID NO: 1. A skilled artisan would be confronted by an undue experimentation burden to discern which tissues specifically express SEQ ID NO: 1, its function, its identity, and what the relevance is (i.e. involvement in a particular disease).

19. On “**(k)**”, as discussed in the previous Office Action (17 September 2003) sequence homology is not predictive of structure or function for potassium channels which are a large and diverse family. Therefore the assertion is a suggestion for SEQ ID NO: 1’s function. As further experimentation is required to confirm SEQ ID NO: 1’s identity and function the asserted utility is not substantial.

20. On “**(l)**”, as discussed in the previous Office Action (17 September 2003) sequence homology is not predictive of structure or function for potassium channels which are a large and diverse family. Therefore the assertion is a suggestion for SEQ ID NO: 1’s function. As further experimentation is required to confirm SEQ ID NO: 1’s identity and function the asserted utility is not substantial. Therefore although it is credible to make fusion proteins (a real-world application) said fusion proteins would have no known function or use. Thusly while the asserted utility is credible (a real world application) it is neither specific nor substantial.

21. On “**(m)**”, as discussed in the previous Office Action (17 September 2003) sequence homology is not predictive of structure or function for potassium channels which are a large and diverse family. Therefore the assertion is a suggestion for SEQ ID NO: 1’s function. As further experimentation is required to confirm SEQ ID NO: 1’s identity and function the asserted utility is not substantial. Therefore although it is credible to make host cells (a real-world application)

Art Unit: 1647

said host cells would have no known function or use. Thusly while the asserted utility is credible (a real world application) it is neither specific nor substantial.

22. On “(n)”, instructions in lieu of data are an invitation to experiment and identify the chromosome where SEQ ID NO: 1 is encoded (if encoded at all). The Examiner takes note of this admission by Applicant that SEQ ID NO: 1 has no known chromosome location as it must be identified by using the instructions provided by Example 12. No specific chromosomal location is disclosed and can only be made certain through additional extensive experimentation. Thus this asserted utility is neither specific nor substantial.

23. On “(o)”, while plausible this utility is neither specific nor substantial. Any polynucleotide can be used to make molecular weight markers. No specific properties inherent in SEQ ID NO: 1 alone makes it desirable or necessary to use in this utility. As the specification discloses an enormous range of tissues both diseased and healthy (pp. 157-178). The Examiner makes note that Applicant admits that no known disease, condition, injury, is associated with SEQ ID NO: 1. A skilled artisan would be confronted by an undue experimentation burden to discern which tissues specifically express SEQ ID NO: 1, its function, its identity, and what the relevance is (i.e. involvement in a particular disease).

24. On “(p)”, instructions in lieu of data are an invitation to experiment. No credible, specific, and substantial utility is disclosed and can only be made certain through additional extensive experimentation. Thus this asserted utility is neither specific nor substantial. As discussed above the question of utility lies with the claimed sequence and not any sequences disclosed in Figure 4 (*Drosophila* data).

25. On “(q)”, instructions in lieu of data are an invitation to experiment. No credible, specific, and substantial utility is disclosed and can only be made certain through additional extensive experimentation. Thus this asserted utility is neither specific nor substantial. As discussed above no disease or condition is identified for SEQ ID NO: 1 therefore while credible this utility is neither specific nor substantial.

26. On “(r)”, Applicant has repeated assertions for the utility of SEQ ID NO: 1 and the polypeptide encoded therein, SEQ ID NO: 2. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. The arguments of counsel cannot take the place of evidence in the record. See MPEP §2145.

27. Claims 1-4, 8, 9, and 16-19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for the reasons set forth at ¶16-18 pp. 13-15 of the previous Office Action (17 September 2003).

28. Applicant traverses this rejection on the following grounds: (a) the present Application discloses how to use the isolated nucleic acids encoding K+βM2 and variants thereof, recombinant vectors and host cell containing nucleic acids to make K+βM2 polypeptides, and to identify modulators thereof useful for the treatment of various disorders, notably immune system disorders, (b) the Patent Office is requiring that applicants submit working examples in order to comply with 35 U.S.C. §112 ¶1, (c) the quantity of experimentation to be performed by one skilled in the art is only one factor in determining whether “undue experimentation” is required to

Art Unit: 1647

make and use the invention, **(d)** no experimentation beyond the application of routine molecular biological techniques is in order to use the claimed polynucleotides (nucleic acids) to make variants and fragments, and **(e)** the Specification teaches how to make, study, and use variants of the claimed polypeptides and polynucleotides. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

29. On **“(a)”**, as noted above arguments of council hold no weight in determining utility. No evidence is present to support the assertions and as discussed in the previous Office Action (17 September 2003) the instant invention lacks utility and therefore is not enabled.

30. On **“(b)”**, no such requirement was set forth in the previous Office Action (17 September 2003) nor has Applicant supplied any working examples or evidence of the claimed sequences utility.

31. On **“(c)”**, while it is true that “undue experimentation” is only one of the *Wands* factors, the Specification as filed constitutes an invitation to experiment in a void of examples and guidance. The skilled artisan is invited first to establish the utility of SEQ ID NO: 1, then make variants, fragments, derivatives, thereof with no guidance as to their structure or function. No specific limitations that would delineate the parameters of what constitutes acceptable variants, fragments, derivatives of SEQ ID NO: 1 are present. Nor is any guidance other than suggestions to experiment on the nature of acceptable variants, fragments, derivatives of SEQ ID NO: 1.

32. On **“(d)”**, no specific guidance has been set forth to practice the invention to the full scope of the claims. The Specification as filed presents an invitation to experiment. First to establish the utility, if any of SEQ ID NO: 1, then to undertake characterization, mutation, and variation to establish all the possible forms of SEQ ID NO: 1. While the methods are present in

the art to perform these experiments, no guidance other than a vague suggestion are given.

Therefore, without sufficient guidance the skilled artisan is left with an insurmountable task of charactering not only SEQ ID NO: 1 but all possible variants, homologues, fragments, and muteins thereof.

33. On “(e)”, the Specification as filed constitutes an invitation to experiment in a void of examples and guidance. The skilled artisan is invited first to establish the utility of SEQ ID NO: 1, then make variants thereof with no guidance as to their structure or function. No specific limitations that would delineate the parameters of what constitutes acceptable variants of SEQ ID NO: 1 are present. Nor is any guidance other than suggestions to experiment on the nature of acceptable variants of SEQ ID NO: 1. The Specification (pp. 57 and Table 3) prophetically considers how one might make variants but as discussed in the previous Office Action (17 September 2003) the state of biochemistry is highly unpredictable.

34. Claims 1-4 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth at ¶19-24 pp. 15-17 of the previous Office Action (17 September 2003).

35. Applicant traverses this rejection on the following grounds: (a) the Specification as filed discloses an extensive list of representative species and relevant characteristics of the species, and (b) *Guidelines for Examination of Patent Applications under the 35 USC 112 ¶1 “Written*

Art Unit: 1647

*Description Requirement*, 66 Fed. Reg. 1099, 1105 (Jan. 5, 2001). Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

36. On “(a)”, the Specification as filed only contains vague suggestions and broad generalizations of the nature of the desired molecules. Molecular biology and protein biochemistry are unpredictable emerging arts {see previous Office Action (17 September 2003)}. The written description requirement cannot be satisfied by suggestion. The *Guidelines for Examination of Patent Applications under the 35 USC 112 ¶1* as quoted by Applicant are insufficient to establish written description. The Specification as filed does not demonstrate material possession of the fragments, derivatives, and muteins claimed. Genes and the proteins they encode represent an art fraught with uncertainty which require extensive and unpredictable experimentation to establish their identity, structure, and function. Thus more extensive guidance and examples are required to satisfy the written description requirement.

37. On “(b)”, the *Guidelines for Examination of Patent Applications under the 35 USC 112 ¶1* as quoted by Applicant is a general rumination on the written description requirement. The fact remains that the Specification as filed only contains vague suggestions and broad generalizations of the nature of the desired molecules. The written description requirement cannot be satisfied by suggestion.

38. As discussed in the previous Office Action (17 September 2003), to satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Thus the inventors can not be said to have “possessed” the claimed invention without knowing for certain the variants, mutations,

derivatives, or fragments that are applicable. Thus the instant application constitutes an invitation to experiment to first identify, then characterize, and then use a class of sequences defined only by sequence of origin

39. As even a highly skilled artisan still must undertake the mammoth task of characterization of SEQ ID NO: 1. This is to be followed by extensive and haphazard trial and error experimentation to isolated, synthesize, and characterize all the variants, homologues, fragments, and mutations encompassed by the claims.

40. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth at ¶¶25-26 pp. 17-18 of the previous Office Action (17 September 2003).

41. Applicant traverses this rejection on the following grounds: (a) Example 12 provides guidance on chromosome mapping. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

42. On "(a)", Example 12 of the Specification is a prophetic consideration of how one would undertake the endeavor to identify allelic variants of SEQ ID NO: 1 (which encodes SEQ ID NO: 2). However, no specific guidance is provided nor are the specific allelic variants disclosed to which the claim is directed. Therefore the claim as currently presented is an invitation to experiment. First the skilled artisan is to undertake the task of locating the chromosome on which SEQ ID NO: 1 is located, then map the chromosome, and then continue the

Art Unit: 1647

experimentation to identify all isoforms that may be considered allelic variants. Since neither concrete definition, nor distinguishing characteristics of what constitutes an allelic variant are provided the skilled artisan is confronted with undue experimentation to fulfill the claims.

43. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth at ¶32 pp. 19-20 of the previous Office Action (17 September 2003).

44. Applicant traverses this rejection on the following grounds: (a) the Specification defines “stringent hybridization conditions” on page 14 lines 16-20. Applicant’s arguments have been taken into consideration and are not found persuasive for the following reasons.

45. On “(a)”, although the claims are read in light of the Specification no particular limitations are to be introduced into the claims unless explicitly stated. Therefore, although a definition of “stringent hybridization conditions” is suggested, it does not limit the claim as currently presented. Further, the definition does not provide for which nucleic acid sequences are to be considered hybridized. The language can cover primers, fragments, probes, antisense, chromosomal DNA, and non-specific DNA commonly used in hybridization assays. Therefore in the absence of explicit limitations the term stringent is considered as broadly as it is presented in the art and thus remains indefinite.

### *Summary*

46. No claims allowed.



Art Unit: 1647

47. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

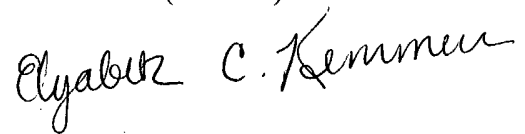
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **<http://pair-direct.uspto.gov>**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN  
March 3, 2004



ELIZABETH KEMMERER  
PRIMARY EXAMINER